## REMARKS

Applicants address the examiner's remarks in the order presented in the Office Action (dated March 25, 2005). All claim amendments are made without prejudice and do not represent acquiescence in any ground of rejection.

### STATUS OF THE CLAIMS

Claims 1-5, 8, 13, 16-32 and 39-41 are pending in the application. Claims 5, 26, and 27 were canceled without prejudice. Claim 13 and 39 were amended for clarity and consistency of claim language. With this Reply, claims 1-4, 8, 13, 16-25, 28-32 and 39-41 will be pending.

Claim 5 was objected under 37 C.F.R. § 1.75(c) as being of improper dependent form.

Claims 26 and 27 stand rejected under 35 U.S.C. § 101 because the claimed invention was directed to non-statutory subject matter.

Claims 1-5, 8, 13, 16-32 and 39-41 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claims 1-5, 8, 13 and 16-18, 23, 24 and 28 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Boden *et al.*, 1999, JAMA 282: 1135-1141).

Claims 1-5, 8, 13, 16-32 and 39-41 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Boden *et al.*, 1999, JAMA 282: 1135-1141).

### CLAIM OBJECTIONS

Claim 5 was objected under 37 C.F.R. § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants canceled claim 5 rendering the examiner's objection moot.

### REJECTIONS

#### Rejections Under 35 U.S.C. § 101

Claims 26 and 27 were rejected under 35 U.S.C. § 101 because the claimed invention was allegedly directed to non-statutory subject matter. Regarding claim 26, the examiner held the view that a report, per se, is non-statutory and is non-functional descriptive material.

Regarding claim 27, as computer-readable medium, comprising a phenotype, the examiner held this to be non-statutory as it contains non-functional descriptive material.

To expedite prosecution, Applicants have canceled claims 26 and 27 without prejudice to expedite prosecution in this matter. Therefore the rejections under 35 U.S.C. § 101 should be withdrawn.

**Rejections under 35 USC § 112– Indefiniteness**

Claims 1-5, 8, 13, 16-32 and 39-41 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

According to the examiner, claim 13 recited "and the genetic sequence of the protease region and reverse transcriptase region". The examiner viewed this as unclear because, according to the examiner, the protease region and the reverse transcriptase region are recited previously. The examiner requested clarification. The examiner stated that since claim 39 recites "receiving a genetics sequence from the Human Immunodeficiency Virus from the patient", there was insufficient antecedent basis for "the patient" in claim 39. The examiner requested clarification.

Regarding claim 13, Applicants clarify for the examiner that the genetic sequence can be chosen from the protease region or the reverse transcriptase region or both the protease and reverse transcriptase regions. Applicants have amended claim 13 for further clarity and consistency of claim language.

Regarding claim 39, Applicants have amended claim 39 for further clarity and consistency of claim language. More specifically, Applicants have amended "the patient" to "a patient".

In view of the foregoing, Applicants respectfully request that the rejection of the claims 1-5, 8, 13, 16-32 and 39-41 under 35 U.S.C. § 112, second paragraph, be withdrawn.

**Rejections under 35 USC § 102– Anticipation**

Claims 1-5, 8, 13 and 16-18, 23, 24 and 28 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Boden *et al.*, 1999, JAMA 282: 1135-1141). Applicants respectfully traverse.

The standard governing anticipation under 35 U.S.C. § 102 requires that a single reference describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art. See Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1120-21, 65 U.S.P.Q.2d 1051, 1054-55 (Fed. Cir. 2002). An anticipating reference must describe all of the elements and limitations of the claim in a single reference, and enable one skilled in the field of the invention to make and use the claimed invention. See Merck & Co., Inc. v. Teva Pharmaceuticals, Inc., 347 F.3d 1367, 1372, 68 U.S.P.Q.2d 1857, 1861 (Fed. Cir. 2003). Absence from the reference of any claimed element negates anticipation. See, *e.g.*, Rowe v. Dror, 112 F.3d 473, 480-81, 42 U.S.P.Q.2d 1550, 1555 (Fed. Cir. 1997) (holding that a "balloon catheter" cannot anticipate a "balloon angioplasty catheter"). See also Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1565 (Fed.Cir.1992); Scripps, 927 F.2d at 1576-77; Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed.Cir.1984).

Every element of the challenged claim need not be expressly delineated in the single prior art reference, but may be inherently disclosed by prior art if "the prior art necessarily functions in accordance with the limitations" of the challenged claim. King, 801 F.2d at 1326; see also Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369 (Fed.Cir.1991), cert. denied, 506 U.S. 817, 113 S.Ct. 60, 121 L.Ed.2d 28 (1992).

Boden *et al.* does not either specifically or inherently disclose every element of the claimed invention. The examiner must clearly show that every element of the claims is disclosed in Boden *et al.*

Boden *et al.* simply does not disclose every limitation of the pending claims. For instance, the examiner stated that Boden *et al.* teaches "searching a relational database (page 1137, column 1, sequence analysis). Applicants respectfully disagree. Applicants teach "searching a relational genotype/phenotype database" in step (c) of claim 1. Applicants direct the examiner's attention to page 19, lines 1-15, of the specification:

> A "relational genotype/phenotype database refers to a database that brings together the knowledge of both a genotypic and phenotypic database. A relational genotype/phenotype database may, for example, comprise one database, two databases, or more than two databases. The genotypic database, or the genotype field of a database, for example, may contain genetic sequence information regarding at least one tested disease producing agent. The genetic sequence information may vary from the entire sequence of a

> disease producing agent to a segment of the sequence of a disease producing agent, to a mutation pattern. In one embodiment, the genetic sequence information may comprise the genetic sequence of tested HIV viruses or the mutation pattern of tested HIV viruses. The phenotypic database, or the phenotype field of a database, for example, may contain phenotypic resistance values for the at least one tested disease producing agent to at least one therapy. For example, the phenotypic resistance values of tested HIV viruses, with a fold resistance determination compared to the reference HIV virus (wild type).

This point alone makes clear that Boden *et al.* does not disclose every element of the claimed invention. Applicants however bring up the following additional points.

The examiner states that Boden *et al.* also teaches "determining a phenotype (page 1137, column 2). The phenotypic analysis in the referenced Boden *et al.* paragraph is done through a so-called recombinant virus assay (from Virologic). Applicants determine the phenotype in step (e) from a phenotype database in claim 1. Applicants direct the examiner's attention to Figure 10B for the examiner's further clarification.

There is also no disclosure of the elements of Applicants' step (d) for "obtaining at least one database phenotype of the at least one database mutation pattern." The phenotypic database of the instant invention contains phenotypic resistance values for the tested HIV with a fold resistance determination compared to the reference of HIV (wild type). (Specification, at page 19, lines 13-15.)

Applicants submit that since there is no disclosure of any one of steps (c), (d) or (e) by Boden *et al.,* Boden *et al.* does not disclose each and every element of claims 1-5, 8, 13 and 16-18, 23, 24 and 28. As such, Applicants respectfully request that the rejection under 35 U.S.C. § 102(a) be withdrawn.

**Rejections under 35 USC § 103– Obviousness**

Claims 1-5, 8, 13, 16-32 and 39-41 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Boden *et al.*, 1999, JAMA 282: 1135-1141).

Applicant respectfully traverses the obviousness rejection because a proper *prima facie* obviousness rejection of claims 1-5, 8, 13, 16-32 and 39-41, as amended, under 35 U.S.C. § 103(a), has not been established.

To establish a proper *prima facie* rejection, the examiner must show:

(1) the references which are available as prior art against the claimed invention;

(2) the motivation (explicit or implicit) provided by the references that would have rendered the claimed invention obvious to one of ordinary skill in the art at the time of the invention;

(3) a reasonable expectation of success;

(4) the basis for concluding that the claimed invention would have been obvious to do, not merely obvious to try; and

(5) the references teach the claimed invention as a whole.

Applicants respectfully submit that at minimum element (5) has not been established for Boden *et al.* It is well established that if any one of these five elements is not established, a proper *prima facie* obviousness rejection cannot be made and the applicants are entitled to a patent. In re Grabiak, 769 F.2d 729, 733, 226 USPQ 870, 873 (Fed. Cir. 1983).

Applicants respectfully assert that the above remarks regarding the rejections under 35 USC § 102 are applicable to the present rejection.

Boden *et al.* does not either specifically or inherently disclose every element of the claimed invention. The examiner must clearly show that every element of the claims is disclosed in Boden *et al.*

Boden *et al.* simply does not disclose every limitation of the pending claims. For instance, the examiner stated that Boden *et al.* teaches "searching a relational database (page 1137, column 1, sequence analysis). Applicants respectfully disagree. Applicants teach "searching a relational genotype/phenotype database" in step (c) of claim 1. This point alone makes clear that Boden *et al.* does not teach the claimed invention as a whole. Applicants however bring up the following additional points.

Furthermore, the examiner states that Boden *et al.* also teaches "determining a phenotype (page 1137, column 2). The phenotypic analysis in the referenced Boden *et al.* paragraph is done through a so-called recombinant virus assay (from Virologic). Applicants determine the phenotype in step (e) from a phenotype database in claim 1. Applicants direct the examiner's attention to Figure 10B for the examiner's further clarification.

There is also no disclosure of the elements of Applicants' step (d) for "obtaining at least one database phenotype of the at least one database mutation pattern." The phenotypic database of the instant invention contains phenotypic resistance values for the tested HIV

with a fold resistance determination compared to the reference of HIV (wild type). (Specification, at page 19, lines 13-15.)

Applicants submit there is no motivation to modify the cited reference to achieve the present invention. Boden *et al.* uses a so-called recombinant virus assay from Virologic. This is not the same way Applicants determine the phenotype in step (e) from a phenotype database per claim 1. The examiner is again directed to review Figure 10(B) for further clarification. Furthermore, Applicants phenotypic database contains phenotypic resistance values for the tested HIV with a fold resistance determination compared to the reference HIV (wild type). There is no motivation from Boden *et al.* to achieve the method as claimed by Applicants.

Because the examiner has failed to properly establish *prima facie* obviousness, Applicants respectfully request withdrawal of the rejection. In view of the foregoing, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 103 be withdrawn.

## CONCLUSIONS

The foregoing represents a *bona fide* attempt to advance the present case to allowance.

Applicants respectfully request:

(1) entry of the amendments to the claims;

(2) reconsideration and withdrawal of the rejections of the claims based on the foregoing remarks and arguments; and

(3) allowance of claims 1-4, 8, 13, 16-25, 28-32 and 39-41.

If the examiner is of a contrary view, the examiner is requested to contact the undersigned attorney at 206.332.1380.

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